AND TRADEMARK OFFICE 1600/28

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

Not Yet Assigned

Group

1614

Applicant

Jochen Wolffgramm

Application No. :

09/851,817

Confirmation No.:

4970

Filed

May 9, 2001

For

USE OF AGONISTS OF THE

GLUCOCORTICOSTEROID AND/OR MINERALO-

CORTICOSTEROID RECEPTORS, IN

PARTICULAR CORTICOSTEROIDS FOR THE

TREATMENT OF ADDICTION

New York, New York November 30, 2001

Hon. Commissioner for Patents Washington, D.C. 20231

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information

Disclosure Statement in the above-identified application.

This Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with

this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Karen Mangasen

James F. Haley, Jr. (Reg. No. 27,794) Karen Mangasarian (Reg. No. 43,772)

Attorneys for Applicant

c/o FISH & NEAVE

1251 Avenue of the Americas New York, New York 10020-1104

Tel.: (212) 596-9000

I Hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to: COMMISSIONER FOR PATENTS WASHINGTON, D.C. 20231 on

November 80,200 Lillian Garcia

Signature of Person Signing



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STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.56

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicant, through his attorneys, make of record the following documents, copies of which are submitted herewith*:

FOREIGN PATENT PUBLICATIONS

Applicant Publication No. Publication Date
Trustees of Boston WO 97/03677 February 6, 1997
University

^{*} A completed Form PTO-1449 (in duplicate) listing these documents is enclosed herewith.

OTHER DOCUMENTS

Albrecht, K. and Lampe, D. 1992. Diagnostik und Therapie von akuten Drogennotfällen. Z. arztl. Fortbild. 85, pp. 701-707.

Capasso, A. et al. 1995. Dexamethasone pretreatment reduces the psychomotor stimulant effects induced by cocaine and amphetamine in mice. Prog. Neuro-psychopharmacol. & Biol. Psychiat. 19, pp. 1063-1079.

Capasso, A. et al. 1996. Dexamethasone selective inhibition of acute opioid physical dependence in isolated tissues. J. Pharmacol. Exp. Therapeut. 276, pp. 743-751.

Capasso, A. et al. 1997. Dexamethasone inhibition of acute opioid physical dependence in vitro is reverted by anti-lipocortin-1 and mimicked by anti-type II extracellular PLA₂ antibodies. *Life Sci.* 61, pp. 127-134.

Ehrenreich, H. et al. 1997. OLITA: an alternative in the treatment of therapy-resistant chronic alcoholics. Eur. Arch Psychiatry Clin. Neurosci. 247, pp. 51-54.

Mantsch, J.R. et al. 1998. Corticosterone facilitates the acquisition of cocaine self-administration in rats: opposite effects of the type II glucocorticoid receptor agonist dexamethasone. J. Pharmacol. Exp. Therapeut. 287, pp. 72-80.

Montgomery, S.P. and Dafny, N. 1987. Cyclophosphamide and cortisol reduce the severity of morphine withdrawal. *Int. J. Immunopharmacol.* 9, pp. 453-457.

Reddy, D.S. and Kulkarni, S.K. 1997. Neurosteroid coadministration prevents development of tolerance and augments recovery from benzodiazepine withdrawal anxiety and hyperactivity in mice. *Methods* Find Exp Clin Pharmacol. 19, pp. 395-405.

Sass, H. et al. 1996. Relapse prevention by acamprosate. Results from a placebo-controlled study on alcohol dependence. Arch. Gen. Psychiatry 53, pp. 673-680.

Sze, P.Y. 1977. The permissive role of glucocorticoids in the development of ethanol dependence and tolerance. *J. Drug Alcohol Dep.* 2, pp. 381-396.

Whitworth, A.B. et al. 1996. Comparison of acamprosate and placebo in long-term treatment of alcohol dependence. Lancet 347, pp. 1438-1442.

CONCISE EXPLANATION OF NON-ENGLISH DOCUMENTS

Albrecht, K. and Lampe, D. describe diagnoses and therapies for acute drug emergencies (overdoses, or acute withdrawal symptoms), such as with amphetamines, cannabis, cocaine, opiates, and inhalants. A copy of an English translation is provided herewith.

None of the above-cited documents, made of record by applicant herein, renders unpatentable, either alone or in combination thereof, the pending claims of this statement.

Applicant request that these documents be (1) fully considered by the Examiner during the course of examination of this application; and (2) printed on any patent issuing from this application. Applicant also request that a copy of the enclosed Form PTO-1449, as considered and initialed by the Examiner, be forwarded to the undersigned with the next communication.

This statement is submitted more than three months from the application filing date but before the mailing date of the first substantive Office Action. In

accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee.

The Director, however, is hereby authorized to charge payment of any additional fee required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Haren Mangasen

James F. Haley (Reg. No. 27,794)

Karen Mangasarian (Reg. No. 43,772)

Attorneys for Applicant

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